

Notice of Allowability**Application No.**

10/568,043

Applicant(s)

JAIN ET AL.

Examiner

ERIC S. OLSON

Art Unit

1623

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment submitted December 4, 2009 and disclaimer submitted March 22, 2010.

2. ☒ The allowed claim(s) is/are 1-3,5-15 and 17-28.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of the:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)

3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 1/5/2010

4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 2/10/2010

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other ____.

/Eric S Olson/
Examiner, Art Unit 1623

Examiner's Amendment

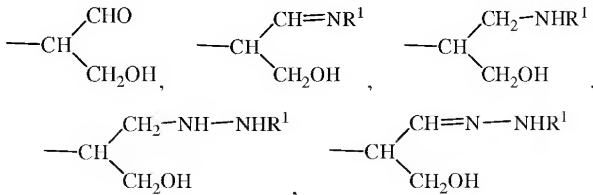
An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kate A. Murashige on March 18, 2010.

Claim 18 is amended as follows:

18. (currently amended): ~~An activated or conjugated derivative of a di-, oligo or polysaccharide~~ having a sialic acid residue at the reducing terminus,

wherein said sialic acid at the reducing terminus has been converted to OX
wherein X is



CH_2CHO , CH_2CHNR^1 , $\text{---CH}_2\text{CH}_2\text{NHR}^1$, $\text{CH}_2\text{CH=N---NHR}^1$, or $\text{CH}_2\text{CH}_2\text{NHNHR}^1$ in which R^1 is H, C_{1-24} -alkyl, aryl C_{2-6} -alkanoyl, or a polypeptide or a protein linked through

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the N terminal or the γ -amine group of a lysine residue thereof, a drug delivery system or is an organic group having a functional substituent adapted for reaction with a sulfhydryl group, and

wherein said di-, oligo-, or polysaccharide ~~has a passivated unit~~ lacks a vicinal diol or aldehyde group at the non-reducing terminal unit.

Detailed Action

This office action is a response to applicant's communication submitted December 4, 2009 wherein claims 1-3, 5-15, and 17-28 are amended, claims 4 and 16 are cancelled, and the drawings are amended. This application is a national stage application of PCT/GB04/03511, filed August 11, 2004, which claims priority to foreign application EP03254959.1, filed August 12, 2003.

Claims 1-3, 5-15, and 17-28 are pending in this application.

Claims 1-3, 5-15, and 17-28 as amended are examined on the merits herein.

Reasons for Allowance

The amended drawings submitted December 4, 2009, have been fully considered and accepted. They are seen to overcome the objections to the drawings of record in the previous office action as all of the drawings are now legible.

Applicant's amendment, submitted December 4, 2009, with respect to the rejection of instant claims 1-3, 5-15, and 17 under 35 USC 112, second paragraph, for reciting the indefinite term, "selective oxidation steps," has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to remove the indefinite terminology. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 4, 2009, with respect to the rejection of instant claim 2 under 35 USC 112, second paragraph, for reciting the

indefinite term, "the vicinal diol group is oxidized," has been fully considered and found to be persuasive to remove the rejection as claim 2 has been amended to remove the indefinite terminology. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 4, 2009, with respect to the rejection of instant claim 5 under 35 USC 112, second paragraph, for reciting the indefinite term, "consisting substantially of," has been fully considered and found to be persuasive to remove the rejection as claim 5 has been amended to remove the indefinite terminology. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 4, 2009, with respect to the rejection of instant claims 19-21 under 35 USC 112, second paragraph, for reciting a structure inconsistent with the base claim 18, has been fully considered and found to be persuasive to remove the rejection as the structure has been replaced with one that is compatible with the structure recited in the base claim. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 4, 2009, with respect to the rejection of instant claims 19-21, 25, and 28 under 35 USC 102(b) for being anticipated by Jennings et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to describe a polysaccharide wherein the modified group -OX is at the reducing end. Therefore the rejection is withdrawn.

Applicant's amendment, submitted December 4, 2009, with respect to the rejection of instant claims 19-21, 25, and 28 under 35 USC 102(b) for being anticipated by US patent 4356170, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to describe a polysaccharide wherein the modified group -OX is at the reducing end as recited in the base claim 18. Therefore the rejection is withdrawn.

Applicant's terminal disclaimer, submitted March 22, 2010, disclaiming the terminal portion of any patent issuing from this application extending beyond the expiration of any patent issuing from copending US application 10/568111, now issued as US patent 7691826, has been reviewed and accepted. The terminal disclaimer is persuasive to remove the rejection of claims 18, 24, and 36 under the doctrine of obviousness-type double patenting for claiming the same invention as claims 1 and 7-9 of 11/568111. Therefore the rejection is withdrawn.

The provisional rejections of claims 19, 21, 25, and 28, of record in the previous office action, for claiming the same invention as claims 1, 2, 5, 7, and 9 of US application 12/375010, claims 1, 2, 5, 9, and 10 of US application 12/375006, and claims 1, 2, 5, 10, and 11 of US application 12/375008, are held in abeyance as none of these three later-filed application have been allowed.

Currently claims 1-3, 5-15, and 17-28 are pending in this application and have been examined on the merits herein. Applicant's amendment submitted December 4, 2009, and terminal disclaimer submitted March 22, 2010, are seen to be persuasive to remove all rejections of record in the previous office action and place the application in condition for allowance. Reasons for allowance are as follows:

The claimed invention is seen to be adequately described and enabled by the specification as originally filed. Therefore the claims meet the requirements of 35 USC 112.

The claimed invention is also seen to be novel and non-obvious over the prior art. Although it is known in the art to oxidize the vicinal diol group of a sialic acid at the non-reducing end of a polysaccharide, as described by Jennings et al. or US patent 4356170, (References of record in previous action) these prior art methods and the resulting conjugates differ from the compounds and methods of the claimed invention in that the activated or conjugated end of the polysaccharide is at the non-reducing rather than the reducing end. One of ordinary skill in the art would have had no motivation in the prior art to modify this procedure by activating the reducing end rather than the nonreducing end of the polysaccharide, especially considering that doing so introduces additional steps into the derivitization procedure and would not be expected to provide any benefit over the prior art methods described above. Therefore the claims meet the requirements of 35 USC 102 and 103.

Accordingly, Applicant's amendment submitted December 4, 2009, and terminal disclaimer submitted March 22, 2010, are sufficient to remove all rejections made in the

prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
4/9/2010